



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics against Somatostatin-Receptor Expressing Neuroendocrine Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating amending an existing license to include a exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the patent application listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to MTTI:

NIH REF NO.	PATENT No. or PATENT APPLICATION No.	FILING DATE	TITLE
E-150-2016-0-US-01	62/333,427	May 9, 2019	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-PCT-02	PCT/US2017/031696	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-CN-03	201780029003X	November 9, 2018	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-EP-04	17796666.0	November 12, 2018	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents

E-150-2016-0-JP-05	2018-558662	November 8, 2018	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents
E-150-2016-0-US-06	16/099,488	November 7, 2018	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license will be granted worldwide and limited to the extent that the above referenced patents or patent applications cover lutetium-177 radiotherapeutics for somatostatin-receptor expressing neuroendocrine tumors.

The invention pertains to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the subject patent estate includes a somatostatin (SST) peptide derivative like octreotate (TATE), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotate (EB-DOTATATE) has been shown by the inventors to provide reversible albumin binding *in vivo* and extended half-life in circulation. When EB-TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB-TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: June 3, 2019.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager,

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development.

[FR Doc. 2019-12708 Filed: 6/14/2019 8:45 am; Publication Date: 6/17/2019]